

ments when so used; (3) in that the carton label failed to bear the common or usual names of the active ingredients; (4) in that the carton label failed to bear the name and place of business of the manufacturer, packer, or distributor; and (5) in that the carton label failed to bear a statement of the quantity of contents.

On July 8, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

547. Misbranding of Special Formula Tablets and McNeal's Laxative Cold Tablets. U. S. v. 88,020 Tablets in containers labeled "Special Formula Tablets—Mono. 'L'" and 41 Dozen Boxes of similar tablets labeled "McNeal's Laxative Cold Tablets." Consent decree of condemnation. Product ordered released under bond to be relabeled. (F. D. C. No. 4037. Sample Nos. 23397-E, 28398-E.)

These tablets were of identical composition. Those in boxes labeled "McNeal's Laxative Cold Tablets" would have been dangerous to health when used according to directions on the label; they also contained false and misleading therapeutic claims. These tablets and the loose ones in the large container failed to bear adequate directions for use and adequate warning statements. The label for the loose tablets also failed to bear the required ingredient statement.

On March 24, 1941, the United States attorney for the District of Maryland filed a libel against the above-named product at Baltimore, Md., alleging that it had been shipped from Buffalo, N. Y., on or about December 16, 1940, by Arner Co., Inc.; and charging that it was misbranded.

Analysis of a sample of the article showed that each tablet contained acetanilid (approximately 1 grain), quinine sulfate (approximately 0.38 grain), a laxative plant drug, and a small amount of atropine.

McNeal's Laxative Cold Tablets were alleged to be misbranded in that they would have been dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, "Directions;—Usual dose. 2 tablets just after meals & at bedtime. Delicate persons may take 1. When relieved take half dose for day or two. Children over 10, $\frac{1}{2}$ adult dose. Limit 4 doses—24 hrs." They were alleged to be misbranded further in that the following statements appearing on the label were false and misleading, "Laxative Cold Tablets Relief for Common Colds * * * A Preparation for Colds * * * The 2nd or 3rd dose should relieve the Cold * * * partly as a result of bowel movement which should occur in 10 hours after taking," since they represented that the article would be efficacious for the purposes recommended; whereas it would not be efficacious for such purposes. The product in both types of containers was alleged to be misbranded in that the labeling did not bear adequate directions for use, and in that the labeling did not bear such adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users. The Special Formula Tablets were alleged to be misbranded further in that the label did not bear the common or usual names of the active ingredients or a statement of the quantities or proportions of acetanilid and atropine contained therein.

On May 12, 1941, Kent Drug Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be relabeled under the supervision of the Federal Security Agency (Food and Drug Administration).

548. Misbranding of Tabknoll Three Bromides Effervescent. U. S. v. 10 Dozen Bottles of Tabknoll Three Bromides Effervescent. Default decree of condemnation and destruction. (F. D. C. No. 3918. Sample No. 34893-E.)

This product contained ammonium, potassium, and sodium bromides, and would be dangerous to health when used as recommended in the labeling. Its labeling also failed to bear adequate directions for use and adequate warnings against its use where such use might be dangerous to health.

On March 6, 1941, the United States attorney for the District of New Jersey filed a libel against 10 dozen bottles of Tabknoll Three Bromides Effervescent at Newark, N. J., alleging that the article had been shipped in interstate commerce on or about January 6, 1941, by H. G. Knoll & Co., Inc., from New York, N. Y.; and charging that it was misbranded.

The article was alleged to be misbranded (1) in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, or suggested in the labeling, namely, (bottle and carton) "Adults, one to two tablets, dissolved in half a glass of water; or as ordered

by the physician.”; (2) in that its labeling failed to bear adequate directions for use; and (3) in that its labeling failed to bear adequate warnings against use where such use might be dangerous to health or against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users.

On September 4, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

549. Misbranding of Dr. Whitehall's Compound Tablets. U. S. v. 642 Boxes of Dr. Whitehall's Compound Tablets. Default decree of forfeiture and destruction. (F. D. C. No. 3681. Sample No. 38625-E.)

On or about January 17, 1941, the United States attorney for the Western District of Wisconsin filed a libel against 642 boxes of Dr. Whitehall's Compound Tablets at La Crosse, Wis., alleging that the article had been shipped on or about November 27 and December 3, 1940, by the Dr. Whitehall Megrimine Co. from South Bend, Ind.; and charging that it was misbranded. It was labeled in part: (Box, carton, and circular) “For Mitigating the Distress and Discomfort of Minor Muscular Aches and Pains,” and (circular only) “If you are subject to attacks on change of weather or exposure, one tablet taken in time will often prevent distress and discomfort.”

Analysis of a sample of the article showed that it contained acetanilid, sodium salicylate, and plant material.

The article was alleged to be misbranded (1) in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, since when used in the dosage and with the frequency or duration prescribed, recommended, and suggested, such use might cause serious blood disturbances, anemia, collapse, and a dependence on the drug; (2) in that the labeling failed to bear adequate directions for use since it did not provide for a limit as to the duration or frequency of administration; (3) in that the labeling failed to bear adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health or against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for the protection of users; and (4) in that the labeling was false and misleading since it created the impression that the article constituted an appropriate treatment for the conditions described therein; whereas it was not a safe and appropriate remedy but was a dangerous drug, and the label failed to reveal the material fact that its use in accordance with the directions might cause serious blood disturbances, anemia, collapse, or a dependence on the drug.

On March 17, 1941, no claimant having appeared, judgment of forfeiture was entered and the product was ordered destroyed.

550. Adulteration and misbranding of Zerbst's Capsules. U. S. v. 139 Packages of Zerbst's Capsules [25-cent size] and 23 Packages of Zerbst's Capsules [50-cent size]. Default decree of condemnation and destruction. (F. D. C. No. 4970. Sample No. 60418-E.)

These products would be potentially dangerous to health when used according to directions and they failed to bear adequate directions for use and warning statements. The capsules in the 25-cent-sized packages contained more acetanilid than the amount stated on the label, and those in the 50-cent-sized packages bore false and misleading therapeutic claims and failed to bear the required ingredient and quantity of contents statements.

On June 24, 1941, the United States attorney for the District of Oregon filed a libel against the above-named products at Portland, Oreg., alleging that they had been shipped on or about January 20, 1941, by the Zerbst Pharmacal Co. from St. Joseph, Mo.; and charging that a portion were adulterated and misbranded and that the remainder were misbranded.

Analyses of samples of the capsules showed that those in the 25-cent packages contained acetanilid ($1\frac{1}{4}$ grains per capsule), together with caffeine, resinous material, camphor, capsicum, aloin, and asafoetida; and that those in the 50-cent packages contained acetanilid ($2\frac{1}{8}$ grains per capsule), together with a laxative plant drug.

The capsules in the 25-cent packages were alleged to be adulterated in that their strength differed from that which they purported or were represented to possess, namely, “Each Capsule contains as active ingredients, Acetanilid 1 Grain”; whereas they contained materially more than 1 grain of acetanilid.

The capsules in the packages of both sizes were alleged to be misbranded: (1) In that they were dangerous to health when used according to the directions